## REMARKS

This application is a national stage filing of PCT/JP2004/004083. Claims 1-4 were present at the time of filing. In response to an initial Office Action, claims 2 and 4 were cancelled and new claims 5-7 were presented. Claims 1, 3 and 5-7 are currently pending in the application.

Claims 3 and 7 are amended above to clarify that the claimed latex reagent/method does not include a step in which the sample being analyzed is pretreated in any way or prediluted to obtain a monomeric preparation of adiponectin prior to assay. Support for the amendment can be found throughout the specification and in particular, at page 4, last full ¶ and page 11, first full ¶).

### *Rejection Under 35 U.S.C.§ 103*

The claims are rejected under 35 U.S.C.§ 103(a) as being unpatentable over Sawai et al. in view of Arita et al. because, according to the Office Action, it would have been obvious to use the adiponectin specific polyclonal antibody of Arita *et al.* in the latex assay of Sawai *et al.*

Sawai *et al.* discloses a basic latex aggregation assay well known to those of skill in the art for determining the presence or absence of an analyte in a sample. The latex particle reagent used in the method has bound to it a molecule that will bind the analyte, for example, an antibody specific for the analyte.

Arita *et al.* discloses the development of an enzyme-linked immunosorbent assay (ELISA) to determine the levels of adiponectin in patient samples. The two-antibody "sandwich" assay disclosed in Arita *et al.* employs a monoclonal anti-adiponectin antibody as the capture antibody and a polyclonal anti-adiponectin antibody as the detection antibody; both antibodies were generated to recombinant adiponectin as antigen (p. 80, column 1, 10-12).

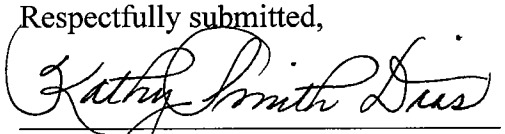
Arita *et al.* discovered that when using the particular combination of antibodies, both of which had been shown by Western blotting to recognize recombinant adiponectin (page 81, column 1, 1st full ¶ under RESULTS), the amount of native adiponectin detected in the plasma samples was lower than expected (page 81, column 2.) In order to get an accurate determination, it was necessary to boil the sample with SDS prior to assay to obtain a monomeric form.

Applicants suggest that Arita *et al.* demonstrates, in general, that use of antibodies does not always produce the expected result and in particular, that the combination of monoclonal and polyclonal (recombinant) adiponectin-specific antibodies did not accurately detect native adiponectin in plasma samples without first treating the sample to denature the adiponectin. Despite their significant value as research tools, the successful use of antibodies in any context is unpredictable and generally, empirically determined. Applicants maintain that one of skill in the art would not have concluded or had an expectation, based on the failure of Arita et al. to detect native adiponectin in plasma samples without first treating the sample to obtain monomeric adiponectin, that the latex agglutination assay of Sawai et al. using latex particles to which the polyclonal adiponectin antibody of Arita *et al.* was linked, would provide an accurate measurement of the amount of adiponectin in the sample. Given the unpredictable nature of antibody use, the claims, as amended above, are not obvious in view of the cited references.

Accordingly, withdrawal of the rejection under 35 U.S.C.§ 103(a) is respectfully requested.

It is respectfully submitted that the above-identified application is now in condition for allowance and favorable reconsideration and prompt allowance of these claims are respectfully requested. Should the Examiner believe that anything further is desirable in order to place the application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,



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